

## REMARKS

### Claim Rejections 35 U.S.C. § 102

The Examiner has rejected pending Claims 1 and 9 under 35 USC §102(b) as being anticipated by Kensey et al. (USPN 5,676,689.) The Examiner states that Kensey discloses each limitation of the claims, including an occlusion member releasably coupled to the elongate member located distally of the distal opening of the elongate member. Applicant respectfully disagrees with this interpretation of the Kensey reference for the reasons discussed below.

First, the Examiner contends that Kensey discloses the releasable aspect of the occlusion member in the Fig. 38 which shows occlusion member 32 located within the patient's tissue. However, Applicant submits that nothing in the Kensey reference teaches the occlusion member being coupled (as required by Claim 1) or attached (as required by Claim 9) to the elongate member. Element 32 is identified by Kensey as an anchor member, and is part of closure device 22. The elongate member cited by the Examiner is element 28, which is described by Kensey as an introducer sheath. Closure device 22, and associated anchor member 32, are not directly associated with introducer sheath 28, but are positioned for delivery within a tubular carrier, element 100 or 102. In turn, tubular carrier 102 slides within introducer sheath 28. In short, there is never any physical contact between closure device 22 and introducer sheath 28. Thus, the Kensey reference does not disclose a "coupled" or "attached" relationship between the two.

Indeed, Kensey describes the interrelationship of these elements as follows:

Referring now to FIGS. 1 and 11 the details of the deployment instrument 20 will now be described. As can be seen the instrument basically comprises a carrier 100 in the form of an elongated tube 102 formed of a somewhat flexible material, such as polyethylene or polyvinyl chloride, *so that the carrier may be freely passed through the introducer sheath into an operative position within the patient's artery*, notwithstanding any curvature of the introducer sleeve which may exist. In accordance with a preferred embodiment of this invention the outside diameter of the tubular carrier 100 is 8 French. The distal end of the tube 102 includes a rigid, e.g., stainless steel, sleeve or bypass tube 104 mounted thereon, to enable it to be inserted through a conventional hemostasis valve 28A (FIGS. 12-14) forming a portion of the introducer sheath 28, through the sheath, and out the distal end thereof into the artery 26. The distal end of the flexible tube 102 necks down into a generally hemicylindrical configuration (See FIG. 1) which includes a

longitudinally extending slit (not shown) therein to enable it to be fit within the bypass tube 104 without buckling.

As can be seen in FIG. 11, *the closure device 22 is located within the distal end of the tubular carrier 100. In particular the anchor member 32 is disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis 106 of the carrier.* The plug member 30 is located within the tube 102 just behind (proximally) of the anchor member and on the opposite side of the central longitudinal axis. In fact the distal end of the plug member overlies the proximal end of the anchor member. The bypass tube 104 includes a reference detent 108 in its periphery located diametrically opposite to the position of the anchor member. The detent 108 serves as a visual guide to help the user orient the instrument to a proper yaw angle with respect to the central longitudinal axis for insertion within the introducer sheath as will be described later. [Kensey, col. 7, line 59 – col. 8, line 27, Emphasis added]

Again, this passage clearly demonstrates that tubular carrier 102 slides freely within introducer 28, and thus, closure device 22 cannot be viewed as being coupled to or attached to it.

Although Applicant believes the previous language of the claims sufficiently distinguish the Kensey reference, it would be desirable to expedite prosecution. To that end, Applicant has introduced language to the claims clarifying that the occlusion member is releasably coupled or attached *at a fixed position* on the distal portion of the elongated member. Even if Kensey were interpreted as teaching some type of joining between the closure device 22 and the introducer sheath 28, the description requiring the tubular carrier to be able to pass freely through the introducer clearly does not constitute a releasable coupling or releasable attachment at a fixed point, distal to the distal opening.

For these reasons, Applicant respectfully submit that Claims 1 and 9 are not anticipated by Kensey and requests that the Examiner withdraw the §102 rejection.

### **Claim Rejections 35 U.S.C. § 103**

Next, the Examiner has rejected pending Claims 1, 3, 9 and 11 under 35 USC §103(a) as being unpatentable over Lee (USPN 5,292,332) in view of Kensey. The Examiner states that Lee discloses a locator device sharing the same limitations as the claimed device, except for the distal opening in communication with a proximal opening on the elongate member. To compensate for

this deficiency, the Examiner cites the Kensey reference, citing the same teaching discussed in the anticipation rejection.

However, as discussed above, Applicant submits that Kensey fails to suggest an elongate member having such a distal opening that is releasably coupled (Claim 1) or releasably attached (Claim 9) to the occlusion member. Rather, the elongate member, introducer 28, having the distal opening 303 is not attached or coupled to the occlusion member, closure device 22, particularly at a fixed location as now required. As such, Kensey does not provide a suggestion to provide an elongated member, with a distal opening and a releasably attached or coupled occlusion member.

For this reason, Kensey fails to compensate for the missing teaching of Lee. Indeed, if one were to modify the Lee reference to feature the distal and proximal openings in an introducer sheath (Kensey's element 28), the analogous structure in the Lee disclosure is arterial sheath 20. This modification would still fail to provide the releasable coupling to the occlusion member, as Lee's occlusion member 22 is also required to slide freely within sheath 20. Accordingly, Applicant respectfully submits that the combination of Lee and Kensey as cited by the Examiner does not suggest the invention as claimed. Therefore, Applicant requests that the Examiner withdraw the §103 rejection of Claims 1, 3, 9 and 11.

#### **Rejoinder of Claims 5 and 7**

As discussed in the previous responses, Applicant requests that method Claims 5 and 7 be rejoined, as they have been amended to share all the structural limitations of the product claims discussed above.

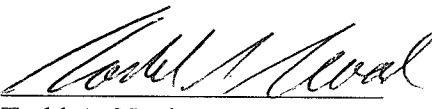
**Conclusion**

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

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